

REMARKS

This Application has been carefully reviewed in light of the Office Action. Applicants respectfully request reconsideration and favorable action in this case.

Section 112 Rejections of Claims 1, 3-8, 12-17, 19-23, 27-33, and 36-39

The Office Action rejects Claims 1, 3-8, 12-17, 19-23, 27-33, and 36-39 under 35 U.S.C. § 112, first paragraph, contending that these claims fail to comply with the written description requirement. Applicants respectfully traverse these rejections for the reasons stated below.

Cancelled independent Claim 1 included the limitation “a body including a conical portion.” The Office Action rejects this limitation and contends that the Examiner could not find support for the limitation in the specification. Applicants respectfully traverse this rejection. However, Claim 1 has been cancelled and new independent Claims 40 and 55 include the limitation “generally conical,” as suggested by the Examiner.

Cancelled independent Claim 1 also included the limitation “a plurality of uninterrupted threads.” The Office Action rejects this limitation and contends that the Examiner could not find support for the limitation in the specification. Applicants respectfully traverse this rejection. However, Claim 1 has been cancelled and new independent Claims 40 and 55 include the limitation “at least one continuous and uninterrupted thread.”

Section 112 Rejections of Claims 3 and 4

The Office Action rejects Claims 3 and 4 under 35 U.S.C. § 112, first paragraph, contending that these claims fail to comply with the written description requirement. Applicants respectfully traverse these rejections. However, Claims 3 and 4 have been cancelled, rendering this rejection moot.

Section 112 Rejections of Claims 32 and 33

The Office Action rejects Claims 32 and 33 under 35 U.S.C. § 112, first paragraph, contending that these claims fail to comply with the written description requirement. Applicants respectfully traverse these rejections for the reasons discussed below.

Cancelled Claim 32 included the limitation “wherein the thread height of each thread is the same.” The Office Action rejects this limitation and contends that the Examiner could not find support for the limitation in the specification. Although Claim 32 has been cancelled, new independent Claim 40 includes the limitation, “a majority of the at least one thread having a substantially constant thread height.” Claim 55 includes a similar limitation directed towards substantially constant thread height. Applicants respectfully submit that the passages at Page 8, Lines 11-13 and Page 10, Lines 4-5 of the specification provide support for these limitations.

Section 112 Rejections of Claims 37 and 39

The Office Action rejects Claims 37 and 39 under 35 U.S.C. § 112, first paragraph, contending that these claims fail to comply with the written description requirement. Applicants respectfully traverse these rejections for the reasons discussed below.

Cancelled Claim 37 included the limitation “wherein a majority of the generally conical body portion has a uniform taper equal to the uniform taper of the majority of crests of the uninterrupted thread.” The Office Action rejects this limitation and contends that the Examiner could not find support for the limitation in the specification. Although Claim 37 has been cancelled, new Claim 41 includes the limitation “wherein the taper of the body is substantially equal to the taper of the at least one thread.” Applicants respectfully submit that the passages at Page 8, Lines 11-13 and Page 10, Lines 4-5 of the specification provide support for the limitation of Claim 41. For example, these passages support the limitation “a majority of the at least one thread having a substantially constant thread height.” Because the majority of the at least one thread has a substantially constant height and the at least one thread is formed around an exterior surface of the body, “the taper of the body is substantially equal to the taper of the at least one thread.”

Similar to Claim 41, Claim 56 includes the limitation “wherein the taper of the body is substantially equal to the taper of the at least one thread.” Therefore, for at least the reasons discussed above with regard to Claim 41, Applicants respectfully submit that Claim 56 is allowable under 35 U.S.C. § 112.

Section 102 and 103 Rejections Using *Lepow*

The Office Action rejects Claims 1, 3, 4, 5, 17, 19, 20, 21, and 36-39 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Pub. No. 2005/0177243 issued to Lepow et al. (“*Lepow*”). The Office Action also rejects Claims 6-8, 12-16, 22-23, and 27-33 under 35 U.S.C. 103(a) as being unpatentable over *Lepow*. Applicants respectfully traverse these rejections. Although the above referenced claims have been cancelled, Applicants submit, concurrent with this response, an Affidavit under 37 C.F.R. §1.131 that establishes a date of conception and reduction to practice prior to February 10, 2004. Therefore, Applicants respectfully submit that *Lepow* may not, alone or in combination, be used to support such rejections.

Furthermore, the Office Action suggests that “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to have the thread dimensions claimed, since where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” See *Office Action*, Page 7. Applicants respectfully traverse the suggestion that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the thread dimension claimed.

Section 102 Rejections Using *Simon*

The Office Action rejects Claims 1, 3-5, 17, 19-21, 36, and 38 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,951,560 to Simon et al. (“*Simon*”). Although Claims 1, 3-5, 17, 19-21, 36, and 38 have been cancelled, Applicants respectfully traverse these rejections to the extent that the Examiner intends to reject any of Claims 40-69 on the same or similar grounds.

Claim 40 is directed to a medical implant including a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot. The body has a length and is tapered along at least a majority of the length. The medical implant further includes at least one continuous and uninterrupted thread formed around an exterior surface of the body and extending at least a majority of the length of the body. The at least one thread is configured to at least partially prevent displacement of a talus without penetrating bone. The at least one thread is tapered with respect to a longitudinal axis of the body. The taper of the at least one thread is generally conical. The medical implant further includes a majority of the at least one thread having a substantially constant thread height and a substantially constant pitch. *Simon* does not disclose each of these limitations.

The Office Action suggests that the implant of *Simon* is “capable of being placed in the sinus tarsi joint.” See *Office Action*, Page 6. However, *Simon* fails to disclose, teach, or suggest that the implant is capable of being placed in the sinus tarsi joint. In fact, *Simon* does not include a single dimension of length, width, or height, let alone a dimension that would enable the Examiner to suggest that the implant is capable of being placed in the sinus tarsi joint. Furthermore, *Simon* clearly discloses that the implant of *Simon* is for “anchoring a bone graft in a bore formed in a bone mass.” See *Simon*, Col. 2, Lines 29-31 (emphasis added). Thus, there is nothing to suggest that the implant is capable of being placed in the sinus tarsi joint, as suggested in the Office Action. As a result, *Simon* does not disclose the medical implant of Claim 40, for example a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot. For at least these reasons, Applicants respectfully submit that Claim 40 is allowable under 35 U.S.C. §102(b). Applicants respectfully request favorable action.

Additionally, *Simon* fails to disclose, teach, or suggest that the at least one thread is configured to at least partially prevent displacement of a talus without penetrating bone. In fact, as discussed above, *Simon* clearly discloses that the implant of *Simon* is for “anchoring a bone graft in a bore formed in a bone mass.” See *Simon*, Col. 2, Lines 29-31. Furthermore, Fig. 33-35 of *Simon* clearly disclose the implant of *Simon* penetrating bone. As a result, *Simon* does not disclose the medical implant of Claim 40, for example at least one thread being configured to at least partially prevent displacement of a talus without penetrating

bone. For at least this additional reason, Applicants respectfully submit that Claim 40 is allowable under 35 U.S.C. §102(b). Applicants respectfully request favorable action.

Claims 41-54 each depend, either directly or indirectly from Claim 40. Therefore, for at least the reasons discussed above with regard to Claim 40, Applicants respectfully submit that Claims 40-54 are allowable under 35 U.S.C. §102(b). Applicants respectfully request favorable action.

Similar to Claim 40, Claim 55 includes limitations related to a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot, and further includes limitations related to at least one thread being configured to at least partially prevent displacement of a talus without penetrating bone. For at least those reasons discussed above with regard to Claim 40, Applicants respectfully submit that Claim 55 is allowable under 35 U.S.C. §102(b). Applicants respectfully request favorable action.

Claims 56-69 each depend, either directly or indirectly from Claim 55. Therefore, for at least the reasons discussed above with regard to Claim 55, Applicants respectfully submit that Claims 56-69 are allowable under 35 U.S.C. §102(b). Applicants respectfully request favorable action.

Dependent Claim 41 is directed to the medical implant of Claim 40, wherein the taper of the body is substantially equal to the taper of the at least one thread. *Simon* does not disclose each of these limitations.

For example, *Simon* clearly discloses that “an aggregate of the crests 16 form a crest taper angle Φ_1 greater than the root taper angle θ_1 .” *See Simon*, Col. 3, Lines 65-66; *see also Simon*, Fig. 2, Fig. 7, Fig. 12, Fig. 14, Fig. 18, Fig. 22., Fig. 26, Fig. 30. As a result, *Simon* does not disclose the medical implant of Claim 41, for example the taper of the body being substantially equal to the taper of the at least one thread. For at least this additional reason, Applicants respectfully submit that Claim 41 is allowable under 35 U.S.C. §102(b). Applicants respectfully request favorable action.

Similar to Claim 41, Claim 56 includes the limitation “wherein the taper of the body is substantially equal to the taper of the at least one thread.” For at least the reasons discussed above with regard to Claim 41, Applicants respectfully submit that Claim 56 is allowable under 35 U.S.C. §102(b). Applicants respectfully request favorable action.

Claim 40, as discussed above, is directed to a medical implant that includes at least one continuous and uninterrupted thread formed around an exterior surface of the body and extending at least a majority of the length of the body. Dependent Claim 43 is directed to the medical implant of Claims 40 and 42, wherein the uniform taper of the at least one thread measures between 15 degrees and 20 degrees. *Simon* does not disclose each of these limitations.

Section 102 Rejections Using *Huebner*

The Office Action rejects Claims 1, 17, 36, and 38 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,964,768 to Huebner (“*Huebner*”). Applicants respectfully traverse these rejections. Although Claims 1, 17, 36, and 38 have been cancelled, Applicants respectfully traverse these rejections to the extent that the Examiner intends to reject any of new Claims 40-69 on the same or similar grounds.

The Office Action suggests that the implant of *Huebner* is “capable of being placed in the sinus tarsi joint.” See *Office Action*, Page 6. However, *Huebner* fails to disclose, teach, or suggest that the implant is capable of being placed in the sinus tarsi joint. For example, *Huebner* clearly discloses that “[i]n installing screw 10, a surgeon first drills bore 52 across bone fragments 48, 50 as shown.” See *Huebner*, Col. 8, Lines 19-20; see also *Huebner*, Fig. 5, Fig. 8A-16B. Thus, nothing suggests that the implant of *Huebner* is capable of being placed in the sinus tarsi joint, as suggested in the Office Action, because a hole must be drilled in bone before the implant of *Huebner* can be used. As a result, *Huebner* does not disclose the medical implant of Claim 40, for example a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot. For at least these reasons, Applicants respectfully submit that Claim 40 is allowable under 35 U.S.C. §102(b). Applicants respectfully request favorable action.

Additionally, *Huebner* fails to disclose, teach, or suggest that the at least one thread is configured to at least partially prevent displacement of a talus without penetrating bone. In fact, *Huebner* clearly discloses that “[t]he radially outer diameter of the threads increases between the leading and trailing ends thus causing each successive thread portion to cut into bone.” See *Huebner*, Abstract (emphasis added). Furthermore, Fig. 5, Fig. 7, and Fig. 8A-16B of *Huebner* clearly disclose the implant of *Huebner* penetrating bone. As a result, *Huebner* does not disclose the medical implant of Claim 40, for example at least one thread being configured to at least partially prevent displacement of a talus without penetrating bone. For at least this additional reason, Applicants respectfully submit that Claim 40 is allowable under 35 U.S.C. §102(b). Applicants respectfully request favorable action.

Furthermore, independent Claim 40 further includes the limitation “a majority of the at least one thread having a substantially constant thread height and a substantially constant pitch.” Applicants respectfully submit that the passages at Page 8, Lines 11-13 and Page 10, Lines 6-9 of the specification provide support for this limitation. Applicants further submit that *Huebner* fails to disclose, teach, or suggest this limitation. For example, *Huebner* clearly discloses that the screw thread of the *Huebner* implant “has a pitch which varies along the length thereof, having a larger pitch near the leading end and a smaller pitch near the trailing end.” See *Huebner*, Col. 5, Lines 44-48.

Additionally, *Huebner* teaches away from an implant including a constant pitch. For example, *Huebner* discloses:

A variation of screw A₃ is shown at A₄ in FIG. 12A. Screw A₄ includes threads D₄ of constant pitch extending along its entire length and differs from screw A₃ in that it tapers from a smaller outside diameter at the leading end to a larger outside diameter at the trailing end. Screw A₄ is shown because it incorporates tapering, which is one of the features of the present invention, however, it is unknown whether such a screw is found in the prior art. Screw A₄ is shown partially installed in a bore F₄ in a near fragment G₄ in FIG. 12A. As screw A₄ is rotated, it moves through fragment G₄ and into a bore H₄ in a remote fragment I₄, as shown in FIG. 12B. Subsequent rotation simply carries screw A₄ further into and through fragment I₄ without any effect on the spacing between the fragments.

See *Huebner*, Col. 2, Line 56 - Col. 3, Line 2. Since *Huebner* teaches away from a constant pitch, *Huebner* does not disclose the medical implant of Claim 40, for example a majority of

the at least one thread having a substantially constant thread height and a substantially constant pitch.

Furthermore, because *Huebner* teaches away from a constant pitch, Applicants respectfully submit that *Huebner* may not, alone or in combination, be used to support rejections of any of the pending claims in the Application. For at least these additional reasons, Applicants respectfully submit that Claim 40 is allowable under 35 U.S.C. §102(b). Applicants respectfully request favorable action.

Claims 41-54 each depend, either directly or indirectly from Claim 40. Therefore, for at least the reasons discussed above with regard to Claim 40, Applicants respectfully submit that Claims 41-54 are allowable under 35 U.S.C. §102(b). Applicants respectfully request favorable action.

Similar to Claim 40, Claim 55 includes limitations related to a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot, and further includes limitations related to at least one thread being configured to at least partially prevent displacement of a talus without penetrating bone and limitations related to a majority of the at least one thread having a substantially constant thread height and a substantially constant pitch. For at least those reasons discussed above with regard to Claim 40, Applicants respectfully submit that Claim 55 is allowable under 35 U.S.C. §102(b). Applicants respectfully request favorable action.

Claims 56-69 each depend, either directly or indirectly from Claim 55. Therefore, for at least the reasons discussed above with regard to Claim 55, Applicants respectfully submit that Claims 56-69 are allowable under 35 U.S.C. §102(b). Applicants respectfully request favorable action.

Section 103 Rejections Using *Simon*

The Office Action rejects Claims 6-8, 12-16, 22-23, and 27-31 under 35 U.S.C. 103(a) as being unpatentable over *Simon*. Although Claims 6-8, 12-16, 22-23, and 27-31 have been cancelled, Applicants respectfully traverse these rejections to the extent that the

Examiner intends to reject any of new Claims 46-54 and 61-69 on the same or similar grounds.

Claims 46-54 incorporate all the elements of independent Claim 40. As discussed above regarding Claim 40, *Simon* does not disclose, teach, or suggest a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot, and at least one thread being configured to at least partially prevent displacement of a talus without penetrating bone. Therefore, for at least the reasons discussed above with regard to Claim 40, Applicants respectfully submit that Claims 46-54 are allowable under 35 U.S.C. 103(a). Applicants respectfully request favorable action.

Similar to Claims 46-54, each of Claims 61-69 incorporate limitations directed a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot, and at least one thread being configured to at least partially prevent displacement of a talus without penetrating bone. Therefore, for at least the reasons discussed above with regard to Claim 40, Applicants respectfully submit that Claims 61-69 are allowable under 35 U.S.C. 103(a). Applicants respectfully request favorable action.

Furthermore, the Office Action suggests that “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to have the thread dimensions claimed, since where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *See Office Action*, Page 7. Applicants respectfully traverse the suggestion that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the thread dimension claimed. For at least the reasons discussed above, Applicants respectfully request reconsideration and allowance of all pending claims.

Section 103 Rejections Using *Huebner*

The Office Action rejects Claims 3-8, 12-16, 19-23, and 27-31 under 35 U.S.C. 103(a) as being unpatentable over *Huebner*. Although Claims 3-8, 12-16, 19-23, and 27-31 have been cancelled, Applicants respectfully traverse these rejections to the extent that the

Examiner intends to reject any of new Claims 43-54 and 58-69 on the same or similar grounds.

Claims 43-54 incorporate all the elements of independent Claim 40. As discussed above regarding Claim 40, *Huebner* does not disclose, teach, or suggest a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot, at least one thread being configured to at least partially prevent displacement of a talus without penetrating bone, and a majority of the at least one thread having a substantially constant thread height and a substantially constant pitch. Therefore, for at least the reasons discussed above with regard to Claim 40, Applicants respectfully submit that Claims 43-54 are allowable under 35 U.S.C. 103(a). Applicants respectfully request favorable action.

Similar to Claims 43-54, each of Claims 58-69 incorporate limitations directed to a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot, at least one thread being configured to at least partially prevent displacement of a talus without penetrating bone, and a majority of the at least one thread having a substantially constant thread height and a substantially constant pitch. Therefore, for at least the reasons discussed above with regard to Claim 40, Applicants respectfully submit that Claims 58-69 are allowable under 35 U.S.C. 103(a). Applicants respectfully request favorable action.

Furthermore, the Office Action suggests that “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to have the thread dimensions claimed, since where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *See Office Action*, Page 8. Applicants respectfully traverse the suggestion that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the thread dimension claimed. For at least the reasons discussed above, Applicants respectfully request reconsideration and allowance of all pending claims.

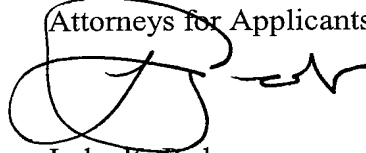
Conclusions

Applicants have made an earnest attempt to place this case in condition for allowance. For the foregoing reasons, and for other apparent reasons, Applicants respectfully request full allowance of all pending Claims. If the Examiner feels that a telephone conference or an interview would advance prosecution of this Application in any manner, the undersigned attorney for Applicants stands ready to conduct such a conference at the convenience of the Examiner.

Applicants hereby take an extension of time for responding to the Office Action dated December 1, 2006 for one month from March 1, 2007 to April 1, 2007. The Commissioner is hereby authorized to charge the one-month extension fee in the amount of \$120.00 and any other fees or credit any overpayments to Deposit Account No. 02-0384 of Baker Botts L.L.P.

Respectfully submitted,

BAKER BOTTS L.L.P.
Attorneys for Applicants

A handwritten signature in black ink, appearing to be 'Luke K. Pedersen', is written over the printed name and firm name.

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Date: April 2, 2007

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